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CORPORATION

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

RICHARD BOWLES; SAMUEL
CANTEY; LUTHER CAULDER;
JERLEAN CONWAY; ROBERT COX;
HAROLD DUREN; ROGER INGRAM;
ANN MCGARY; ALAN ORLOMOSKI;
INEZ ORTIZ; MARLINE RANDALL; and
BETTY WITHROW,

Plaintiffs,

v.

SMITHKLINE BEECHAM
CORPORATION d/b/a
GLAXOSMITHKLINE and McKESSON
CORPORATION,

Defendants.

Case No. CV-07-6328 JCS
(Pending Ruling on Motion to Relate Cases)

**DEFENDANT SMITHKLINE
BEECHAM CORPORATION d/b/a
GLAXOSMITHKLINE'S
MEMORANDUM OF LAW IN
OPPOSITION TO PLAINTIFFS'
MOTION TO REMAND**

DATE: January 18, 2008
TIME: 9:30 a.m.
COURTROOM: A
JUDGE: Mag. Joseph C. Spero

THIS DOCUMENT RELATES TO THE FOLLOWING CASES:

*Bone, et al. v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and
McKesson Corporation*; Case No. CV-07-5886 MHP.

*Bowles, et al. v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and
McKesson Corporation*; Case No. CV-07-6328 JCS (ruling on motion to relate pending).

Fisher v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and McKesson

1 Corporation; Case No. CV-07-5889 MHP.

2 *Hall v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and McKesson*
3 *Corporation*; Case No. CV-07-5887 MHP.

4 *Hefner, et al. v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and*
5 *McKesson Corporation*; Case No. CV-07-6050 JL (ruling on motion to relate pending).

6 *Jefferson v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and*
7 *McKesson Corporation*; Case No. CV-07-5888 MHP.

8 *Thornton v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and*
9 *McKesson Corporation*; Case No. CV-07-5890 MHP.

10 *Upshaw v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and*
11 *McKesson Corporation*; Case No. CV-07-5891 MHP.

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1 **I. INTRODUCTION**

2 This is one of a number of cases that have recently been filed against defendant
 3 SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE (“GSK”) involving the prescription drug Avandia®. Plaintiffs’ counsel, The Miller Firm, has filed
 4 Avandia cases in both state and federal courts. In the California cases only, The Miller
 5 Firm has named McKesson Corporation (“McKesson”), a California-based wholesale
 6 pharmaceutical distributor, as a defendant.¹ By naming McKesson as a defendant, The
 7 Miller Firm is attempting to take advantage of the so-called “forum defendant rule” to
 8 contend that removal was procedurally defective. *See* 28 U.S.C. § 1441(b). The forum
 9 defendant rule is a waivable non-jurisdictional rule. *See Lively v. Wild Oats Mkts., Inc.*,
 10 456 F.3d 933, 940 (9th Cir. 2006).

11 Plaintiffs’ joinder of McKesson is fraudulent, however, and the citizenship of
 12 McKesson must be disregarded for purposes of 28 U.S.C. § 1441(b). In addition to
 13 diversity jurisdiction, this Court also has federal question, or “arising under,” jurisdiction
 14 over this matter because numerous counts of Plaintiffs’ complaint turn on violations of
 15 federal law.

16 Accordingly, Plaintiffs’ Motion to Remand should be denied.

17 **II. BACKGROUND**

18 Plaintiffs commenced this action in the Superior Court of the State of California
 19 for the County of San Francisco on November 8, 2007 asserting claims of (1) negligence;
 20 (2) negligent failure to warn; (3) negligence per se; (4) negligent misrepresentation; (5)
 21 breach of express warranty; (6) breach of implied warranty; (7) strict products liability –
 22 defective design; (8) strict products liability – manufacturing and design defect; (9) strict
 23 products liability – failure to adequately warn; (10) fraudulent misrepresentation; and
 24 (11) violations of California Unfair Trade Practices and Consumer Protection Law.
 25

26
 27 ¹ The facts relating to McKesson are attested in the Declaration of Greg Yonko, a true and correct copy of
 28 which is attached as Exhibit “D” to the declaration of Krista L. Cosner in Support of Notice of Removal and
 Removal by Smithkline Beecham Corporation d/b/a GlaxoSmithKline (hereinafter “Cosner Decl. ISO Removal”).

1 Plaintiffs aver that collectively, “Defendants” or “Defendants GSK and McKesson,”
 2 defectively designed and manufactured Avandia; concealed knowledge of unreasonably
 3 dangerous risks associated with Avandia; failed to conduct adequate and sufficient pre-
 4 clinical testing and post-marketing surveillance of Avandia; failed to provide FDA with
 5 complete and adequate information regarding Avandia; failed to warn consumers and/or
 6 their health care providers of certain risks associated with Avandia; failed to utilize
 7 adequate and non-misleading labeling; and made affirmative misrepresentations and
 8 omissions regarding the alleged risks of Avandia.

9 On December 13, 2007, GSK removed this action to this court, based on diversity
 10 jurisdiction under 28 U.S.C. § 1332, and federal question jurisdiction under 28 U.S.C. §
 11 1331 and the principles set forth in *Grable & Sons Metal Prods., Inc. v. Darue Eng’g &*
 12 *Mfg*, 125 S.Ct. 2363 (2005).² See Notice of Removal (filed December 13, 2007). GSK
 13 also sought the transfer of this action to the Multidistrict Litigation, In re Avandia
 14 Marketing, Sales Practices and Products Liability Litigation, MDL 1871, and provided
 15 the JPML with notice of this action pursuant to the procedure for “tag along” actions set
 16 forth in the rules of the JPML.

17 Plaintiffs now move to remand this case to the Superior Court of the State of
 18 California for the County of San Francisco. As explained below, Plaintiffs’ motion is
 19 without merit, and it should be denied.

20 **III. ARGUMENT**

21 **A. This Court Should Defer Ruling On Plaintiffs’ Remand Motion** 22 **Pending MDL Transfer**

23 As GSK argued in its Motion to Stay All Proceedings Pending Transfer by the
 24 JPML, this Court should not rule on Plaintiffs’ Remand Motion, but should stay this case
 25 until it is transferred to the Avandia MDL, MDL No. 1871. Allowing the transferee court
 26 _____

27 ² At the time of removal, GSK had not been served with Plaintiffs’ Complaint. Service was made upon
 28 defendant McKesson on November 14, 2007.

1 to decide this and the other pending Motions to Remand will conserve the resources of
 2 the Court, will ensure consistent rulings, and will not prejudice the Plaintiffs to any
 3 significant degree. *See* Defendant's Motion to Stay All Proceedings; *see also Landis v.*
 4 *North Am. Co.*, 299 U.S. 248 (1936).

5 In the Vioxx litigation, this Court and other Northern District judges were faced
 6 with several cases removed on grounds identical to the grounds for removal of this case;
 7 namely, that McKesson was fraudulently joined, and, when its citizenship was properly
 8 disregarded, there was complete diversity of citizenship between plaintiffs and
 9 defendants. Ruling on plaintiffs' remand motions was deferred in favor of staying the
 10 cases pending transfer to the MDL on the grounds of judicial economy and consistency.
 11 *See Johnson v. Merck & Co., Inc.*, Case No. C 05-02881 MHP, Slip Op. at 2 (N.D. Cal.
 12 October 4, 2005) ("In light of the number of cases presenting issues similar to this action
 13 and the need for judicial consistency with respect to those cases, this court finds that the
 14 interest of judicial economy favors staying this action pending its transfer to [the Vioxx
 15 MDL.]."); *Johnson v. Merck & Co., Inc.* Case No. C 07-00067 WHA, Slip Op. at 4 (N.D.
 16 Cal. March 8, 2007) ("It would be an inefficient use of resources to unnecessarily
 17 duplicate the efforts of the transferee judge, who will undoubtedly face most (if not all) of
 18 the same issues in dealing with the other pending remand motions. Staying the
 19 proceedings will best serve the interests of judicial economy."); *Dante v. Merck & Co.,*
 20 *Inc.*, Case No. C07-00081 JW, Slip Op. at 2 (N.D. Cal. Feb. 27, 2007) (staying case with
 21 pending remand motion where McKesson was named as co-defendant because "[i]n light
 22 of the number of other cases presenting issues similar to this action and the need for
 23 judicial consistency with respect to those cases, the Court finds that the interest of
 24 judicial economy favors staying this action pending its transfer to the MDL Proceeding").
 25 *See also Murphy v. Merck & Co., Inc.*, No. C 06-04794 MHP, Slip Op. (N.D. Cal. Sept.
 26 22, 2006) (staying case pending transfer to MDL proceeding where McKesson was
 27 named as a co-defendant); and *Parker v. Merck & Co., Inc.*, No. C 07-2333 SI, Slip Op.
 28 at 2 (N.D. Cal. June 26, 2007) (staying case pending transfer to MDL and deferring

1 ruling on remand where case removed on the basis of fraudulent joinder).

2 For the identical reasons, this Court should defer ruling on Plaintiffs' Motion to
3 Remand, and should stay all proceedings in this case until it is transferred to the Avandia
4 MDL.

5 **B. This Court Has Diversity Jurisdiction Over Plaintiffs' Claims**

6 If the Court does consider Plaintiffs' motion prior to MDL transfer, it should deny
7 Plaintiffs' motion to remand this action because Plaintiffs have fraudulently joined
8 McKesson, a citizen of California, as a defendant. The fraudulent joinder doctrine
9 requires courts to disregard the citizenship of local defendants when no viable cause of
10 action has been stated against the resident defendant, or when evidence presented by the
11 removing party demonstrates that there is no factual basis for the claims pleaded against
12 the local defendant. *See Morris v. Princess Cruises, Inc.*, 236 F.3d 1061, 1067 (9th Cir.
13 2001); *see also Ritchey v. Upjohn Drug Co.*, 139 F. 3d 1313, 1318-19 (9th Cir. 1998). A
14 defendant is also considered fraudulently joined when "the plaintiff fails to state a cause
15 of action against the resident defendant, and the failure is obvious according to the settled
16 rules of the state." *Hamilton Materials, Inc., v. Dow Chemical Corporation*, 494 F.3d
17 1203, 1206 (9th Cir. 2007) quoting *McCabe v. General Foods Corp.*, 811 F. 2d 1336,
18 1339 (9th Cir. 1987).

19 As set forth below, Plaintiffs cannot state a cause of action against the distributor
20 McKesson because (a) Plaintiffs do not allege that McKesson handled the Avandia
21 Plaintiffs ingested; (b) Plaintiffs' allegations against "defendants" and McKesson are
22 inconsistent with their allegations against GSK; and (c) a wholesale distributor cannot be
23 liable under any reasonable view of California law for alleged defects in a drug it did not
24 make, or for the alleged inadequacy of warnings over which it had no control. In sum,
25 there is no reasonable likelihood that Plaintiffs can prevail on their claims against
26 McKesson. These deficiencies demonstrate that McKesson has been fraudulently joined
27 as a defendant in this matter, warranting this Court to disregard McKesson's citizenship
28 so that it may exercise its jurisdiction based on the complete diversity of the parties, and

1 to deny Plaintiffs' motion to remand.³

2 **1. Plaintiffs' Factual Allegations Against McKesson Do Not**
 3 **Provide an Adequate Causal Connection Between McKesson**
 4 **and Their Alleged Injuries**

5 First, McKesson was fraudulently joined because Plaintiffs do not even allege that
 6 McKesson distributed the Avandia they took.

7 To state a personal injury claim against a pharmaceutical distributor, a plaintiff
 8 must, as a threshold matter, allege an actual connection between the distributor's alleged
 9 conduct and the plaintiff's purported injury. *See, e.g., Huntman v. Danek Medical, Inc.*,
 10 No. 97-2155-IEG RBB, 1998 WL 663362, at *4, *6-*7 (S.D. Cal. July 24, 1998) (strict
 11 liability, negligence, negligence per se claims require proof that alleged misconduct was
 12 directed at plaintiff or plaintiff's physician); *Service by Medallion, Inc. v. Clorox Co.*, 44
 13 Cal. App. 4th 1807, 1818 (1996) ("In order to recover for fraud, as in any other tort, the
 14 plaintiff must plead and prove the 'detriment proximately caused' by the defendant's
 15 tortious conduct.") (citing Cal. Civ. Code § 3333). Where, as here, plaintiffs fail to
 16 allege such a link, federal courts have recognized that non-diverse distributors are
 17 fraudulently joined and cannot defeat diversity jurisdiction. *See In re Rezulin Prods.*
 18 *Liab. Litig.*, 133 F. Supp. 2d 272 (S.D.N.Y. 2001) ("Rezulin II") (denying motion to
 19 remand where plaintiffs named a non-diverse defendant and alleged that a distributor
 20 defendant was "in the business of distributing and selling the pharmaceutical" on grounds
 21 that plaintiffs did not allege that the defendant "actually sold" the pharmaceutical product
 22 to the plaintiffs).

23 In its Notice of Removal, GSK noted that the factual allegations against
 24 McKesson were insufficient to establish a connection between McKesson and Plaintiffs'
 25 alleged injuries. In response, Plaintiffs charge that "GSK asks this Court to ignore the
 26 numerous times McKesson is identified by name within Plaintiffs' Complaint, and the

27 ³ While the citizenship of the California plaintiff, Ann McGary, is not diverse from that of McKesson, the
 28 citizenship of McKesson, as explained below, must be ignored because McKesson's joinder was fraudulent. When
 McKesson's citizenship is disregarded, there is complete diversity of citizenship.

1 factual detail of McKesson's activities by name." Plaintiffs' Notice of Motion and
 2 Motion to Remand with Supporting Memorandum ("Pls'. Br.") at 3:10-12.

3 In fact, Plaintiffs do not even allege that the Avandia ingested was distributed by
 4 McKesson, *see Lyons v. American Tobacco Co.*, 1997 U.S. Dist. LEXIS 18365, *18-19
 5 (S.D. Ala. 1997) (there is "no better admission of fraudulent joinder of [resident
 6 defendants]" than the failure of the plaintiff "to set forth any specific factual allegations"
 7 against them). Only one paragraph of Plaintiffs' Complaint contains any direct
 8 allegations against McKesson. *See* Pls'. Compl. at 30:4-7 ("Defendant McKesson
 9 packaged, distributed, supplied, sold, placed into the stream of commerce, labeled,
 10 described, marketed, advertised, promoted, and purported to warn or to inform users
 11 regarding the risks pertaining to, and assuaged concerns about the pharmaceutical
 12 Avandia.") attached as Exhibit "A" to Cosner Decl. ISO Removal. The remaining
 13 allegations are directed at "Defendants" or against "Defendants GSK and McKesson."
 14 *See, e.g., id.* at 58 ("...defendants failed to timely and reasonably warn of material facts
 15 regarding the safety and efficacy of Avandia..."); 89 ("Defendants GSK and McKesson
 16 marketed, distributed, supplied and sold the subject product..."). Courts have held that
 17 generic allegations against multiple defendants are insufficient to create a causal
 18 connection between a plaintiff's alleged injuries and the conduct of a single defendant.
 19 *See e.g., Aronis v. Merck & Co., Inc.*, CIV. S-05-0486 WBS DAD, 2005 U.S. Dist.
 20 LEXIS 41531, *3 (E.D. Cal. May 3, 2005); *see also In re PPA, MDL No. 1407*, Slip Op.
 21 at 5 (W.D. Wa. Nov. 26, 2002) (allegations directed toward "defendants" or "all
 22 defendants" insufficient).

23 In *Aronis*, for example, the plaintiff alleged that her heart attack was caused by the
 24 prescription medication Vioxx, Merck – the manufacturer of Vioxx – removed the case to
 25 federal court on grounds that all the requisites of diversity jurisdiction existed. In an
 26 effort to defeat diversity, the plaintiff in that case, as here, named distributor-defendant
 27 McKesson who, like the plaintiff, was a citizen of California. The court concluded that
 28 complete diversity existed and removal was proper because the plaintiff made "no

1 allegation that McKesson ever handled the specific pills that were allegedly the cause of
 2 her injuries.” *Id.* at *3. According to the court, McKesson was fraudulently joined
 3 because “plaintiff does not allege that McKesson contributed in any way to her injuries,
 4 only that McKesson is a distributor.” *Id.* at *4.

5 The rationale in *Aronis* applies with equal force here. Plaintiffs’ allegations
 6 against McKesson are general, conclusory, and provide no more than the insufficient
 7 contention that McKesson – like many other companies – distributed Avandia to
 8 pharmacies in California. Such “bare-bones” allegations are plainly incapable of
 9 supporting a claim against McKesson and, thus, McKesson is fraudulently joined. *See id.*
 10 at *3-4 (“allegation that McKesson is a major distributor of Vioxx, even though taken as
 11 true at this state, is not enough to support a claim against McKesson”).

12 **2. Plaintiffs’ Purported Allegations Against McKesson are** 13 **Inconsistent with Their Central Allegations Against GSK**

14 Second, McKesson was fraudulently joined because Plaintiffs’ allegations against
 15 McKesson are inconsistent with their core allegations against GSK.

16 The crux of Plaintiffs’ lawsuit rests on allegations regarding GSK’s design and
 17 manufacture of Avandia, and assertions that GSK failed to adequately warn against
 18 Avandia’s alleged side effects and concealed important safety information. *See Pls’*
 19 *Compl.* at 31-44 (Cosner Decl. ISO Removal, Exh. “A”). Yet, Plaintiffs also purport to
 20 assert that McKesson was responsible for the warnings included in Avandia’s labeling,
 21 *see id.* at 30:4-7, and that both “defendants” were responsible for these warnings. *See id.*
 22 at 58. These allegations are inconsistent and contradictory, and courts have frequently
 23 viewed such inconsistencies as evidence of fraudulent joinder. For instance, in *Baisden*
 24 *v. Bayer Corp.*, 275 F.Supp. 2d 759, 762-763 (S.D. W. Va. 2003), a pharmaceutical
 25 manufacturer removed a product liability case to federal court, asserting that the plaintiff
 26 fraudulently joined a local physician to defeat diversity. *See id.* The district court agreed
 27 and denied remand. *See id.* The complaint alleged that the defendant manufacturer had
 28 concealed and misrepresented information about the safety of the drug, but also that the

1 physician was negligent for failing to monitor the patient and warn of the drug's side
 2 effects. *See id.* The plaintiffs in *Baisden* repeatedly alleged that the manufacturer
 3 concealed and misrepresented facts regarding the drug, and yet also asserted that the
 4 doctor knew or should have known the truth in spite of the manufacturer's
 5 misrepresentations. *See id.* Observing the contradictory and irreconcilable nature of
 6 those positions, the district court ruled that the plaintiff had fraudulently joined the
 7 physician and disregarded the physician's local citizenship. *See id.*

8 Numerous other courts have reached the same conclusion as the court in *Baisden* –
 9 that plaintiffs should not be able to defeat diversity jurisdiction when it is clear that their
 10 claims against the in-state defendant are wholly inconsistent with the substance of their
 11 lawsuit.⁴

12 For this reason too, McKesson is fraudulently joined.

13 **3. Under California Law Plaintiffs Cannot Prove a Cause of Action** 14 **Against McKesson For Plaintiffs' Alleged Injuries**

15 Finally, even if McKesson had distributed plaintiffs' Avandia, it would still be
 16 fraudulently joined because there would still be no basis for holding McKesson liable
 17 under California law.

18 Under no reasonable view of California law can a wholesale distributor be liable
 19 for injuries allegedly caused by defects in a drug it did not make, nor by allegedly
 20 inadequate warnings over which it had no control. *See Yonko Dec.* at 6, 7 ("McKesson
 21 did not manufacturer, produce, process, test, encapsulate, label, [or] package Avandia®,

22 ⁴ *See In re PPA*, slip op. at 6-7 (pharmacy defendant fraudulently joined where the allegations that
 23 "manufacturer defendants concealed material facts regarding PPA through product packaging, labeling, advertising,
 24 promotional campaigns and materials, and other methods . . . directly undermines and contradicts the idea that [the
 25 resident retail defendant] had knowledge or reason to know of alleged defects"); *In re Rezulin Prod. Liab. Litig.*, 133
 26 F. Supp. 2d 272, 290 (S.D.N.Y. 2001) (resident retail pharmacies facing failure to warn claims fraudulently joined
 27 where "the theory underlying the complaint [was] that the manufacturer defendants hid the dangers of Rezulin from
 28 plaintiffs, the public, physicians, distributors and pharmacists – indeed, from everyone"); *Wiggins v. Am. Home*
Prods. Corp., No. CV-01-J-2303-NW, 2001 WL 34013629 (N.D. Ala. Oct 2, 2001) (in-state pharmacy was
 fraudulently joined where plaintiffs made no reasonable allegation against the pharmacy); *In re Rezulin Prods. Liab.*
Litig., 2003 U.S. Dist. LEXIS 28, MDL No. 1348, Case No. 02-Civ. 3583 (S.D.N.Y. Jan. 6, 2003) (finding
 fraudulent joinder where the failure to warn claims against a physician were premised on knowledge allegedly
 withheld).

1 nor does it make any representations or warranties as to the product’s safety or efficacy;”
 2 “[McKesson] only delivered the unopened boxes that contained the drug”) (Cosner Decl.
 3 ISO Removal, Exh. “D”). Arguing that such liability does exist under California law,
 4 Plaintiffs rely almost exclusively on a series of Vioxx decisions from a single judge from
 5 the Central District of California. *See* Pls’. Br. at p. 7:4-7. Those isolated decisions,
 6 however, are not binding on this Court, and as explained below, do not represent correct
 7 applications of California law.

8 California tort law treats prescription drugs differently from other products. For
 9 example, California law unequivocally bars strict liability causes of action for design
 10 defect in the prescription drug context. *See Brown v. Superior Court*, 44 Cal. 3d 1049,
 11 1061 (1988) (“a drug manufacturer’s liability for a defectively designed drug shall not be
 12 measured by the standards of strict liability”). In *Brown*, the California Supreme Court
 13 held that a manufacturer is not strictly liable or liable for breach of express or implied
 14 warranties for injuries caused by a prescription drug “so long as the drug was properly
 15 prepared and accompanied by warnings of its dangerous propensities that were either
 16 known or reasonably scientifically knowable at the time of distribution.” *Id.* at 1069. In
 17 California – as in virtually every other state – the duty to warn about a drug’s risks runs
 18 directly from the manufacturer to the physician (*i.e.* the “learned intermediary”), and then
 19 from the physician to the patient. *See Brown*, 44 Cal. 3d at 1061-62, n.9.; *Carlin v.*
 20 *Superior Court*, 13 Cal. 4th 1104, 1116 (1996). Accordingly, case law makes clear that,
 21 under the “learned intermediary doctrine,” distributors such as McKesson owe no duty to
 22 individual patients. Because the pharmaceutical company, not the distributor, has a duty
 23 to warn physicians of the risks associated with medications and medical devices, courts
 24 have repeatedly concluded that distributors are fraudulently joined. *See, e.g., Barlow v.*
 25 *Warner-Lambert Co.*, Case No. CV 03 1647 R (RZx), slip op. at 2 (C.D. Cal. April 28,
 26 2003) (“The Court finds that there is no possibility that plaintiffs could prove a cause of
 27 action against McKesson, an entity which distributed this FDA-approved medication
 28 [Rezulin] to pharmacists in California;” motion to remand denied); *Skinner v. Warner-*

1 *Lambert Co.*, Case No. CV 03 1643-R (RZx), 2003 WL 25598915 at *2 (C.D. Cal. April
 2 28, 2003); *Murphy v. E.R. Squibb & Sons, Inc.*, 40 Cal. 3d 672, 680-81 (1985) (under the
 3 learned intermediary doctrine, retail pharmacies can have no general duty to warn
 4 consumers of effects of prescription drugs); *In re Baycol Prods. Litig.*, MDL No. 1431,
 5 No. 02-139, 2002 WL 32155268 (D. Minn. May 24, 2002) (retail distributor of
 6 prescription drugs fraudulently joined); *Schaerrer v. Stewart's Plaza Pharmacy*, 79 P.3d
 7 922, 929 (Utah 2003) (declining to extend duty to warn to retail distributor of
 8 prescription diet drug as long as [their] "ability to distribute prescription drugs is limited
 9 by the highly restricted FDA-regulated drug distribution system in this country . . .");
 10 *Legg v. Wyeth*, 428 F.3d 1317 (11th Cir. 2005) ("[t]he Multidistrict Litigation Court . . .
 11 concluded that this joinder can 'only be characterized as a sham, at the unfair expense not
 12 only of [Wyeth] but of many individuals and small enterprises that are being unfairly
 13 dragged into court simply to prevent the adjudication of lawsuits against [Wyeth], the real
 14 target, in a federal forum.'").

15 Furthermore, pharmaceutical warnings are highly regulated by the Food & Drug
 16 Administration ("FDA"), which militates against imposing any separate duty to warn on
 17 pharmacies and pharmaceutical distributors. The FDA closely regulates pharmaceutical
 18 manufacturing, and it controls the testing of medicines and the methods by which they
 19 are marketed, including the contents of warning labels. *Brown*, 44 Cal. 3d at 1059, fn.
 20 12. The federal regulations provide specific requirements for all aspects of the medicine,
 21 the standards to be followed in manufacturing (21 C.F.R. §211, *et. seq.*), the standards for
 22 wholesale distribution (§203.50), the contents of its labeling, including warnings
 23 (§201.57), and permissible representations to be made in advertisements (§202, *et seq.*).
 24 The regulations also state that a manufacturer may list only known risks and not
 25 theoretical possibilities, and that no prescription medicine may go to a distributor like
 26 McKesson unless the labeling complies with federal regulations and is approved by the
 27 FDA. *See* 21 C.F.R. §201.57(d); 21 C.F.R. §201.59.

28 Once the labeling is approved, the information found therein cannot be altered

1 without FDA approval. *See* 21 U.S.C. § 331(k); *Brown v. Superior Court*, 44 Cal. 3d at
 2 1069 n. 12 (noting that the FDA regulates the testing, manufacturing, and marketing of
 3 drugs, including the content of their warning labels). Both drug manufacturers and
 4 distributors are prohibited from causing the “alteration, mutilation, destruction,
 5 obliteration, or removal of the whole or any part of the labeling” of an FDA-approved
 6 drug held for sale. 21 U.S.C. § 331(k).

7 As a distributor, McKesson had no duty to warn Plaintiffs, assuming it distributed
 8 the Avandia ingested by Plaintiffs in the first place. Nor could McKesson have given
 9 additional or different warnings without violating federal law. The FDA approved all
 10 Avandia warnings and marketing materials. Had McKesson provided alternative, non-
 11 FDA approved warnings, or warnings inconsistent with those approved by the FDA, it
 12 would have been in violation of federal law prohibiting false or misleading labeling and
 13 the alteration of FDA-approved labeling (21 U.S.C. §331, subd. (k), (o); 21 U.S.C.
 14 §352(a), (f); 21 C.F.R. 201.56, 201.57), and could have resulted in an enforcement action,
 15 fines or criminal penalties. 21 U.S.C. §§331, subd. (b), (k), 352, subds. (a), (f), 333,
 16 subd. (a). No duty can be found where it requires a party to violate the law to fulfill it.

17 These authorities lead to two inescapable conclusions that control this motion.
 18 First, the distributor McKesson had no duty to warn Plaintiffs of anything and, thus,
 19 cannot be held liable to Plaintiffs – even if it did distribute the Avandia that Plaintiffs
 20 allegedly ingested. Second, not only did McKesson have no duty to Plaintiffs, it could
 21 not have given additional warnings even if it wanted to. The FDA approved all Avandia
 22 warnings and marketing materials. Had McKesson provided additional, non-FDA
 23 approved warnings, or warnings inconsistent with those approved by the FDA, they
 24 would have been in violation of federal law prohibiting false or misleading labeling and
 25 the alterations of FDA-approved labeling (21 U.S.C. §§ 331, subd. (k), (o); 21 U.S.C. §
 26 352(a), (f); 21 C.F.R. 201.56, 201.57), and could have resulted in an enforcement action,
 27 fines or criminal penalties. 21 U.S.C. §§ 331, subd. (b), (k), 352, subds. (a), (f), 333,
 28 subd. (a).

Both the federal regulation of warnings provided with prescription drugs and the common law approach to pharmaceutical product liability claims convey the underlying policy preference that one set of consistent and approved warnings accompany drugs like Avandia. The duty to warn lies with the manufacturer, and any alteration of those warnings by a distributor would violate federal law. As such, Plaintiffs may not proceed against McKesson on a theory of failure to warn.

In short, there is no theory of liability under which Plaintiffs could prevail against McKesson. Accordingly, McKesson's citizenship should be ignored for purposes of the forum defendant rule, and this Court has diversity jurisdiction over this case.

C. This Court Has Federal Question Jurisdiction Based on Plaintiffs' Claims Which Raise Questions Of Federal Law

Since diversity jurisdiction over this matter is clear, GSK need not address in detail the second ground for removal, federal question jurisdiction.

Plaintiffs' complaint contains many assertions that depend on construction and application of federal statutes and regulations, and therefore this Court has federal question jurisdiction over this matter pursuant to 28 U.S.C. § 1331 and the principles set forth in *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005).

There are several federal questions in plaintiffs' claims, and it is in the national interest that there be a federal forum for claims that attack the federally-approved labeling of a prescription medicine. Count III of the Complaint, for example, explicitly alleges that GSK violated the Food Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., and that GSK illegally promoted an unsafe drug for public use and failed to warn the FDA, doctors and consumers of the risks of Avandia. *See* Pls'. Compl. at 36-38, 43, 65 (Cosn. Decl. ISO Removal, Exh. "A").⁵

⁵ GSK notes that plaintiffs have made several unsupportable arguments in addressing the federal aspects of this case. For example, plaintiffs state that the burden of updating the label rests squarely with the defendant and argues that the preemption defense was "abolished," when, "[o]n September 27, 2007, the Prescription Drug User Free [sic] Authorization Act (PDUFA), H.R. 3580, was signed into law [and], for the first time, placed the burden of updating the warning label of a prescription drug squarely on the drug company." Pl.'s Br. at 11-12. The Act that

1 To the extent this Court seeks further exposition of the presence of federal issues
 2 and federal question jurisdiction, GSK requests leave to file an additional brief in which
 3 to present its position.

4 **IV. CONCLUSION**

5 This Court has both diversity jurisdiction and federal question jurisdiction over
 6 Plaintiffs' Complaint. Accordingly, Plaintiffs' Motion to Remand should be denied.

7
 8 Dated: December 26, 2007

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9 /S/

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 15 CORPORATION

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 27 was signed by President Bush on September 27, 2007 is entitled the Food and Drug Administration Amendments
 28 Act of 2007, 110 P.L. 85; 121 Stat. 823 (FDAAA), codified at 21 U.S.C. §355. It is evident from the plain language
 of the provision in question that the FDAAA does not alter the responsibility of the drug manufacturer with respect
 to labeling, and it has absolutely no effect on any preemption defense. *See* 21 U.S.C. § 355(o)(4)(I).